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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,260	03/04/2002	Ira C. Felkner	61-2U5	8046

570 7590 05/25/2004

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2005 MARKET STREET, SUITE 2200  
PHILADELPHIA, PA 19103-7013

EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/091,260	<b>Applicant(s)</b> FELKNER ET AL.	
	<b>Examiner</b> Ralph Gitomer	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 11-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

The Response to Restriction received 5/13/04 has been entered and claims 11-36 are currently pending in this application. Please update the specification regarding related cases. This application is a CIP of 09/563,707. Priority is granted to the filing date of this application, 3/4/2002.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Tautvydas in view of Wyatt.

Tautvydas (5,795,730) entitled "Rapid Read Out Biological Indicator" teaches in column 1 lines 40-43, the need for a more rapid determination has led to apparatus and procedures which provide an indication of sterilization effectiveness in less time. In column 2, as spores germinate, they absorb water and lose the capability of scattering light in spore containing suspensions. The method may be employed with a variety of sterilization methods that are typically used including steam, ethylene oxide, radiation, heat, chemicals. An incubation time is shown as 4-20 minutes. In column 3 first full paragraph, linear reaction velocities may be readily determined using known light scattering techniques by passing light through exposed spores. Spore germination rates may be determined using nephelometers based on light scattering in view of the light scattering behavior of suspended spores. In column 4 lines 25-33, the rate of spore germination allows a prediction of the number of viable surviving spores. In column 5, last paragraph, *Bacillus stearothermophilus* and *subtilis* spores are shown. In column 6 lines 43-46, a germinating medium provides rapid read out times. See the claims.

The claims differ from Tautvydas in that they include limitations directed to multiangle light scattering specifically.

Wyatt (3,770,351) entitled "Optical Analyzer for Microparticles" teaches in column 1 line 12, analysis of spores. In column 1 lines 63-66, detectors are positioned at a number of different angles in relation to the point of intersection between the light and particle stream.

Art Unit: 1651

It would have been obvious to one of ordinary skill in this art at the time the invention was made to employ known light scattering techniques in the method of Tautvydas such as those taught by Wyatt who teaches multi angle light scattering because Tautvydas teaches germinating spores lose the ability to scatter light because they change shape by absorbing water. One would have a high expectation of success in employing known light scattering measurements for their known function with the expected result. The presently claimed photometers are known and nephelometers employ an angle between incident and determined light.

Regarding controls, the use of controls in this art is old, no novelty is seen in comparing the difference between treated and not treated spores.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in every occurrence.

In claim 11 line 1, "the viability" lacks antecedent basis. In claim 11(b) "the treated" lacks antecedent basis. In claim 25 line 1 "the efficacy" lacks antecedent basis. In claim 25(b) it is unclear if the indicator has or has not been exposed. In claim 27 trademarked names in claims are improper.

Art Unit: 1651


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Tautvydas (6,187,555) teaches spores for sterilants.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Ralph Gitomer  
Primary Examiner  
Art Unit 1651

RALPH GITOMER  
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GROUP 1200